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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,629	04/23/2001	Jason W. Trobaugh	13297.00019	3963

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EXAMINER	
EDWARDS, PATRICK L	
ART UNIT	**PAPER NUMBER**
2621	

DATE MAILED: 03/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/840,629	TROBAUGH ET AL.	
	Examiner	Art Unit	
	Patrick L Edwards	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21,23-33 and 35-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *5-10,13,24-30,32,33,36-42,44,46,49 and 50* is/are allowed.

6)☒ Claim(s) *1-4,11,12,14-21,23,31,35,45,47,48 and 51-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 October 2004* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. The response received on 22 October 2004 has been placed in the file and was considered by the examiner. An action on the merits follows.

Response to Arguments

2. The applicant's arguments, filed on 22 October 2004, have been fully considered. A response to these arguments is provided below.

Drawing Objections

Summary of Argument: The previous office action required new corrected drawings because of the objections raised by the official draftsperson on the Form PTO-948. Applicant has attached corrected drawings.

Examiner's Response: The attached corrected drawings are still unacceptable for reasons which will be stated in the below drawing objection.

37 CFR 1.75 Claim Objections

Summary of Argument: In the previous office action, claims 22-44, 46-48, and 50 were objected to under 37 CFR § 1.75(a). These objections were based on several unclear phrases from the previous claims. Applicant has amended the claims accordingly, and argues that the prior objection should be withdrawn.

Further, the examiner objected to claims 1-21, 23, 31-33, 35, 45, 46, 48, and 50 under 37 CFR § 1.75(d)(1) because the meaning of the term 'microstructure' as recited in the claims, was not clear in light of the specification. The examiner requested clarification on this issue. In response to the objection, applicant submits that the plain meaning of the term 'microstructure' is intended throughout the specification and the claims

Examiner's Response: The examiner appreciates the applicant's efforts to resolve the 1.75(a) issue by amending the claims. The previous objections are hereby withdrawn.

The examiner appreciates the applicant's efforts to resolve the 1.75(d)(1) issues by providing further explanation on the term 'microstructure.' The previous objections are hereby withdrawn.

35 USC 112, Second Paragraph Rejections

Summary of Argument: In the previous office action, claims 47-50 were rejected under 35 USC § 112(2) because the structure of the claims was not properly described in the specification. Applicant has amended the specification by adding four drawings to clarify the structure.

Examiner's Response: The prior rejection is hereby withdrawn.

Prior Art Rejections

Summary of Argument: In the previous office action, claims 1, 3, 4, 12, 16, 17, 22, 23, 31, 34, 35, 43, 45, 47 and 48 were rejected under 35 USC § 102(b) as being anticipated by Sheehan (USPN 6,106,466). With respect to claim 1—which will be treated as a representative claim—applicant has amended the claim by adding the limitation that the microstructure is "sub-wavelength microstructure." Applicant argues that Sheehan does not teach this limitation, and that the claims are therefore allowable over the prior art. More specifically, applicant alleges that the teachings of the Sheehan reference are limited to "large scale structure" (see remarks page 21) and therefore do not read on the amended claim limitation.

Examiner's Response: The examiner disagrees. The term "sub-wavelength microstructure" as described in the applicant's specification, is simply referring to the roughness of a surface (see paragraph [0034]). Sheehan discloses determining the smoothness of a surface (sheehan col. 14 line 45). As is well known, determining surface roughness is the same thing as determining surface smoothness. Both are simply measures of image texture. Thus, by applicant's own description, Sheehan teaches the newly added claim limitation.

If we were to disregard the applicant's description of surface roughness as sub-wavelength microstructure, however, the Sheehan reference would be insufficient to meet all the limitations of the amended claim. Sheehan discloses determining surface smoothness, but is silent with respect to wavelength of the of the ultrasound signal. In order to err on the side of caution, the examiner has decided not to rely on the applicant's specification. The previous 102 rejection is therefore withdrawn.

A new grounds of rejection—necessitated by amendment—is provided below.

Drawings

3. New corrected drawings are required in this application for the following reasons:

- Figures 1-6 are objected to under 37 CFR § 1.84(b) because the drawings are of insufficient quality so that all details are reproducible in the printed patent.
- Figures 3-6 are objected to under 37 CFR § 1.84(p) because the numbers and reference characters are not plain and legible and are not at least 0.32cm in height.
- Figures 7-10 are objected to because they lack any reference characters (see 37 CFR § 1.84(p)).

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Specification

4. The disclosure needs to refer to added drawings 7-10. The examiner has received the specification amendment which included the brief description of Figures 7-10, and acknowledges that these descriptions are acceptable. However, the parts of the detailed description of the invention which describe the subject matter illustrated by the newly added drawings need to refer to those drawings. Of course, this further requires that the

newly added drawings be given reference identifiers (as is mentioned in the above paragraph). Once these drawings are correctly labeled, the specification should be amended accordingly, so that it refers to the drawings and provides a detailed description.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 1-4, 11, 12, 14-19, 21, 23, 31, 35, 45, 47, 48, 51, 52, and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan et al. (USPN 6,106,466) and Seyed-Bolorforosh (USPN 5,841,889) (herein 'Seyed').

With regard to claim 1, Sheehan et al. disclose a method for forming an image model, comprising the steps of: a. developing imaging system characteristics (see Sheehan Fig. 11: Reference numeral 212 referring to a physics model of ultrasound reflection and attenuation in and around heart (i.e. imaging system characteristics).); b. developing gross shape (see Sheehan Fig. 11: Reference numeral 210 referring archetype shape (i.e. gross shape).); c. developing microstructure (see Sheehan Fig. 11: Reference numeral 216 referring to structural model of cardiac anatomy (i.e. microstructure).); d. incorporating the imaging system characteristics, the gross shape and the microstructure to form the image model (see Sheehan Fig. 11: As can be seen in the figure, 210, 212, and 216 are incorporated to form the ultrasound imaging model.).

Further referring to claim 1, the above paragraph aptly states that Sheehan teaches the limitation of developing microstructure. The amended claim, however, requires developing sub-wavelength microstructure. This limitation is not expressly disclosed in Sheehan. Seyed, also in the field of ultrasound image processing, discloses developing sub-wavelength microstructure (Seyed col. 3 lines 45-50: The reference discloses developing microsture (i.e. the texture of the tissue, which determines the type of tissue) which is small compared to wavelength (i.e. sub-wavelength). The 'reflectors' disclosed in the cited passage is simply referring to the tissue that the sound waves are reflecting off of (see col. 4 lines 15-16).).

It would have been obvious to one reasonably skilled in the art at the time of the invention to determine Sheehan's smoothness parameters (sheehan col. 14 line 45) as a sub-wavelength microstructure as taught by Seyed. Such a modification would have allowed for the ability to distinguish between different tissue types This would have been a very desirable result, because "The ability to distinguish between tissue types in a clinical ultrasound image is very important for the detection of diseased tissue" (see Seyed col. 3 lines 59-61).

Claim 2, which is representative of claim 11, calls for the imaging system characteristics to be developed using a three-dimensional point spread function.

This element is absent from Sheehan et al.; however, Seyed, in the same field of endeavor of image processing and the same problem solving area of ultrasound imaging discloses such a feature (see column 3, lines 46-50: The reference describes the use of a three-dimensional point spread function.).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify Sheehan et al. by describing the imaging system characteristics using a three-dimensional point spread function as taught in Seyed because the use of such a three-dimensional point spread function gives the system the "ability to distinguish between different tissue types in a clinical ultrasound image" (see Seyed: column 3, lines 59-60).

With regard to claim 3, Sheehan et al. disclose that the image model includes a data likelihood enabling a statistical inference to formulate underlying characteristics (see column 14, lines 22-26: The reference describes that the image model is based on a knowledge base of ventricular shapes defined by rotations, translations, and scaling of the set of training data (i.e. data likelihood) with the estimated covariance matrix for each of the vertices of the archetype shape (i.e. enabling a statistical inference).).

With regard to claim 4, Sheehan et al. disclose that the data likelihood is developed using image pixel based statistics (see column 14, lines 22-26: The reference describes that the training data set (i.e. data likelihood) is developed using an estimated covariance matrix for each of the vertices (i.e. image pixel based statistics).).

With regard to claim 12, Sheehan et al. disclose that tissue is characterized by a reflectivity function (see column 10, lines 8-15: The reference describes that the epicardial surface of the heart (i.e. tissue) can be characterized by the reflected intensity of a sound wave (i.e. reflectivity function) as provided for in equation (5).)

With regard to claim 16, Sheehan et al. disclose that the gross shape is described by a triangulated surface (see Fig. 8: As can be seen in the figure, the archetype model (i.e. gross shape) is described by a triangulated surface.).

With regard to claim 17, Sheehan et al. disclose that the triangulated surface includes a set of triangular elements defined by respective vertices and edges of the triangular elements (see Fig. 8: As can be seen in the figure, the triangulated surface includes a set of triangular elements defined by respective vertices and edges of the triangular elements.).

With regard to claim 23, Sheehan et al. disclose creating a represenative physical model of image formation (see Fig. 11: This figure illustrates the construction of a physical model.) by performing steps (a), (b), (c), and (d), which have already been discussed with respect to claim 1 above.

Sheehan further discloses creating a representation of the physical model to form the probabilistic model (see Fig. 1 and column 17, lines 13-20: The reference describes that the mesh model (i.e. physical model is adjusted to yield a three-dimensional surface that best represents the shape of the patient's heart (i.e. probabilistic model).).

With regard to claim 31, Seyed discloses that the microstructure is formed using image pixel-based statistics (Seyed figure 5 and accompanying description).

With regard to claim 51, Sheehan further discloses that the gross shape is described by a volume of space (sheehan col. 1 line 66 – col. 2 line, and elsewhere throughout the specification).

With regard to claim 52, Sheehan fails to explicitly recite that the acoustic properties of the volume of space are represented by multiple discrete scatterers distributed across the volume. However, this limitation is inherent in the Sheehan disclosure as it is well established in the field of ultrasonic imaging that any object to be imaged is comprised of discrete targets which are distributed across the volume of the object. These discrete cell targets, which are found in tissue, for example, are commonly referred to as "scatterers."

With regard to claim 54, Sheehan discloses estimating the shape of an object (sheehan col. 14 line 39).

Regarding claim 14: this claim contains limitations discussed above, and adds the limitation that a radio frequency (RF) image is used for forming the image model. The claim further recites that this RF image is represented by a sum of scaled and delayed point spread functions (PSF). The use of PSF's in the Seyed reference was discussed with respect to claim 2 above. Seyed further discloses that the images are formed from RF signals (seyed col. 8 line 32). This is very common in the art, as it is well established that backscatter/reflection/speckle signals are radio frequency signals. Seyed further discloses that the signals are delayed (seyed col. 9 line 43), and that they are scaled (seyed col. 9 lines 7-15: The reference describes different ways of mapping (i.e. scaling) the signals. These signals are then summed (seyed col. 10 lines 33-48).

Referring to claim 15, the limitation of tissue being characterized by a discrete scatterer (or reflector) model was discussed above with respect to claim 52.

With regard to claim 18, all of the limitations of the claim have been addressed above.

Referring to claim 19, Seyed further discloses that the spatial locations of scatterers are parametrized by a scatterer concentration and a surface roughness (seyed col. 4 lines 34-58).

Referring to claim 21, Seyed further dislcoses that each discrete scatterer is a sub-wavelength perturbation in the surface that scatters in the direction of the transducer (seyed col. 3 lines 41-55).

With regard to claims 35, 45, 47, and 48 which merely call for a computer readable medium that configures a computer to perform the methods discussed above, Sheehan disclose such a computer readable medium since all of the processing performed in Sheehan et al. is performed by CPU 52 (see Fig. 2).

7. Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Seyed as applied to claim 19 above, and further in view of Liu et al. (5,339,815). With regard to the limitations of this claim, the aforesaid combination discloses modeling surface roughness by using scatterers (or reflectors) which reflect transmitted sound waves in a direction normal to a triangulated surface. However, this combination fails to expressly disclose modeling surface roughness using a gaussian distribution. Liu, on the other hand, discloses modeling surface roughness as a gaussian distribution (Liu col. 5 line52 – col. 6 line 4). It would have been obvious to one reasonably skilled in the art at the time of the invention to to modify sheehan and seyed's image model forming method by using a gaussian distribution to model surface roughness as taught by Liu. Such a modification would have allowed for the use of a well know distribution algorithm with a probability function. Such an algorithm would aid in the formation of a probabilistic model.

8. Claim 53 is rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Sheehan and Seyed as applied to claim 1 above, and further in view of Slayton et al. (USPN 6050943). The arguments as to the relevance of the aforesaid combination as applied above are incorporated herein.

Claim 53 adds the feature of an image model being used to estimate the the temperature of an object. The combination of Sheehan and Seyed is silent with respect to temperature estimations. Slayton, however, discloses an ultrasonic transducer system that provides imaging capabilities and temperature estimation capabilities (see Slayton abstract). It would have been obvious to one reasonably skilled in the art at the time of the invention to augment Sheehan and Seyed's method for image modeling by adding temperature estimation capabilities as taught by Slayton. Such a modification would have allowed for a more robust system capable of developing image models of objects and also estimating the temperature of those objects.

Allowable Subject Matter

9. Claims 5-10, 13, 24-30, 32, 33, 36-42, 44, 46, and 49-50 are allowed.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

- Shokrollahi et al. (USPN 6,200,266) teaches producing high-resolution ultrasound images of tissue substantially free of speckle.
- Watanabe (USPN 5,031,154) teaches the use of a reflection coefficient defined by a delta (impulse) function in a 3D ultrasound object imaging system.
- Ustuner et al. (USPN 6,309,356) teaches high frame rate, sequential transmission of ultrasound waves in a 3D object modeling environment.
- Daft et al. (USPN 6,245,016) teaches a convolution model that allows for depth varying pulse responses and tissue-type changes.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick L Edwards whose telephone number is (703) 305-6301. The examiner can normally be reached on 8:30am - 5:00pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bhavesh Mehta can be reached at (703)308-5246. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick L Edwards Art Unit 2621

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